REMARKS

Claims 22-24 are currently pending.

Claims 22-23 stand rejected under 35 USC 112, first paragraph, on the ground that the specification is not enabling for reducing levels of any soybean storage protein comprising transforming a soybean seed with a chimeric gene which comprises a nucleic acid fragment encoding all or a portion of a soybean glycinin or beta-conglycinin seed storage protein.

Claim 22 recites that the quantity of **one or more** members of a class of soybean seed storage protein subunits is reduced when compared to soybean seeds not comprising the chimeric gene of step (a), and wherein the class of soybean seed storage protein subunits is selected from the group consisting of: glycinin and β-conglycinin.

Furthermore, all of the claims specifically recite that the soybean storage proteins are beta-conglycinin and/or glycinin. Thus, the instant invention does not recite all soybean storage proteins. Rather, it specifically recites beta-conglycin and/or glycinin.

It was stated on page 4 of the Office Action that "(a) majority of transgenic embryos failed to exhibit reduced levels of all conglycinin subunits, and (b) expression of an unrelated delta-12 desaturase gene in one transgenic embryo. . . ."

Claim 22 specifically recites that a quantity of **one or more** members of a class of soybean storage subunits is reduced. The claims do not recite that all members of class of soybean storage subunits be reduced. Claim 22 recites that **one or more are reduced.**

Furthermore, it is well known to those skilled in the art that individual transgenic plants carrying the same construct may differ in expression levels; this phenomenon is commonly referred to as "position effect".

Thus, in the present invention different individual transformants may vary in the effectiveness of suppression of the target seed protein. The person skilled in the art will know that special considerations are associated with the use of antisense or cosuppression technologies in order to reduce expression of particular genes.

U.S. Patent Nos. 5,190,931, 5,107,065 and 5,283,323 have taught the feasibility of these techniques, but it is well known that their efficiency is unpredictable. Accordingly, the person skilled in the art will make multiple genetic constructs containing one or more different parts of the gene to be suppressed, since the art does not teach a method to predict which will be most effective for a particular

gene. Furthermore, even the most effective constructs will give an effective suppression phenotype only in a fraction of the individual transgenic lines isolated.

For example, World Patent Publications WO93/11245 and WO94/11516 teach that when attempting to suppress the expression of fatty acid desaturase genes in canola, actual suppression was obtained in less than 1% of the lines tested. In other species the percentage is somewhat higher, but in no case does the percentage reach 100.

This should not be seen as a limitation with respect to the present invention, but instead as practical matter that is appreciated and anticipated by the person skilled in this art. Accordingly, the skilled artisan will develop methods for screening large numbers of transformants. The nature of these screens will generally be chosen on practical grounds, and is not an inherent part of the invention. A preferred method will be one which allows large numbers of samples to be processed rapidly, since it will be expected that the majority of samples will be negative (see also page 13, lines 1-28 of the instant specification).

It was stated on the bottom of page 4 of the Office action that examples 2 and 3 of the specification do not suggest that the promoter region of beta-conglycinin was capable of suppressing expression of one or more class of non-conglycinin soybean seed storage proteins.

First of all, the claimed invention pertains to conglycinin and/or beta-conglycinin. Reference to non-conglycinin sobean seed storage proteins is unwarranted given that the claims focus on conglycinin and beta-conglycinin.

Example 2 of the instant specification describes the preparation of a construct containing the *Glycine max* microsomal delta-12 desaturase cDNA (FAD2) linked in an antisense orientation to the ß-conglycinin promoter. Transgenic lines showed increased levels of oleic acid, consistent with suppression of FAD2, and a reduction α and α' subunits of ß-conglycinin. **Thus, the promoter region of region ß-conglycinin was found to be capable of suppressing expression of the ß-conglycinin subunits.**

Example 3 of the instant specification describes the preparation of an antisense construct containing the ß-conglycinin promoter linked in an antisense orientation to the full length α cDNAs. The transgenic clones all gave rise to at least one somatic embryo in which the expression of both α and α ' was suppressed.

Applicants respectfully submit that this is consistent with and supports the instant invention as currently claimed. The scope of the instant invention pertains to

conglycinin and beta-conglycinin and does NOT pertain to non-conglycinin soybean seed storage proteins.

It is stated on page 5 of the Office Action that while Example 4 provides guidance on making cosuppression constructs containing the cDNAs corresponding to the group I cDNA of Glycinin and the group II cDNA of Glycinin linked in sense direction to the β-conglycinin promoter, "however, Example 4 fails to address the core issue of reducing the expression levels of of glycinin, β-conglycinin and other seed storage proteins in a soybean seed by transforming said seed with a construct comprising an antisense or sense sequence of glycinin or β-conglycinin." It was also further maintained that no transgenic embryos with reduced levels of soybean seed storage proteins were produced in Example 4 .

The core issue is reducing expression levels of glycinin and/or beta-conglycinin. Reference to other seed storage proteins is in error and not part of the currently claimed invention.

Example 4 describes the preparation of cosuppression constructs containing the cDNAs corresponding to the group I cDNA of Glycinin and the group II cDNA of Glycinin linked each in sense direction to the ß-conglycinin promoter. The glycinin cDNAs share about 85% sequence identity within the same group and only about 42% to 46% sequence identity between the groups.

It is respectfully submitted that instant application provides sufficient guidance on making cosuppression constructs containing the cDNA corresponding to the group I and group II cDNA of Glycinin linked each in sense direction to the β-conglcyinin.

This is further supported by Dr. Fader's declaration. Dr Fader's original declaration dated June 27, 2001 was submitted in connection with the prosecution of Application No. 09/108,010 now U.S. Patent No. 6,362,399, and was submitted with Applicant's last response. Dr. Fader's declaration shows that all the glycinin subunits were suppressed when truncated forms of the G1 and G4 subunits were expressed in a sense orientation under the control of a KTi promoter. Thus, Dr. Fader's declaration provides additional data for the embodiment's described in the specification.

Accordingly discussion in the specification, the results presented in Figures 5 and 7, and the results shown in the declaration demonstrate a reduction in seed storage protein levels (β-conglycinin or glycinin) relative to a control.

In view of the foregoing discussion, withdrawal of the rejection of claims 22-24 under 35 USC §112, first paragraph, is respectfully requested.

Claims 22-23 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

It was stated on page 7 of the Office Action that "Applicant did not present any arguments against the rejection. Accordingly, it is maintained that there is a lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. Accordingly, the rejection is maintained."

The foregoing statement is not correct. It was stated the reasons presented with respect to the enablement rejection were believed to be applicable with respect to the written description rejection.

Thus, it is respectfully submitted that the rejection based on failure to satisfy the written description requirement was addressed. Whether the Examiner finds this persuasive is another matter. However, arguments were presented. It is incorrect to state the no arguments were presented.

It was stated in the Office Action mailed September 21, 2007 that the specification describes transgenic soybean seed embryos transformed with a DNA construct comprising expression of sense or antisense fragments of nucleic acid fragments derived from a nucleotide sequence encoding soybean β–conglycinin and exhibited reduced levels of β–conglycinin. No transgenic soybean embryos or seeds with reduced levels of glycinin using sense or antisense based cosuppression are described.

The Written Description Guidelines (MPEP 2163) state that the written description requirement is satisfied when a patent application describes a claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. "Possession may be shown by actual reduction to practice, or by showing that the invention was 'ready for patenting' such as by the disclosure of the drawings or other descriptions of the invention that are sufficiently specific to enable a person skilled in the art to practice the invention."

The following is submitted in support thereof:

1. The specification discloses that expression of truncated glycinin subunits would suppress glycinin (Example 4).

2. Methods to prepare DNA fragments comprising truncated versions of the different glycinin subunits were set forth in the specification (Example 4). The specification also described how to use these nucleic acid fragments to practice the invention.

3. The fragments corresponding to the glycinin Group I (G1) and Group II (G4) described in Example 4 of the specification (page 26 at line 3 through page 27 at line 31) were joined in a transcription unit under the control of the KTi promoter and used for bombardment into somatic embryo tissue. The transcription unit containing KTi promoter/G1/G4/KTi 3' end was cloned into the Bam HI site of pKS18HH. Plasmid pKS18HH is described in the application on page 15 at line 40 through page 16 at line 3 and is shown in the application's Figure 3. The plasmid used for bombardment contained:

a) the KTi promoter/G1/G4/KTi 3' end

b) the T7 promoter/HPT/T7 Terminator Sequence

c) the CaMV 35S promoter/HPT/NOS 3' end

d) the vector sequences from pSP72 with the beta-lactamase coding region removed.

Bombardment and analyses were conducted as described in the specification on page 17 at line 10 through page 18 at line 37.

4. The results submitted with Dr Gary Fader;'s previously submitted declaration (an example of which is shown in the SDS PAGE gel of protein extracted from seeds of lines derived from regenerated plants) indicate that all the glycinin subunits are suppressed in some of the lines.

Accordingly, withdrawal of the rejection of claims 22-24 under 35 USC §112, first paragraph, is respectfully requested.

Claims 22-24 remain rejected under 35 U.S.C.102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Trueblood et al. (US Patent No. 4,267,118 ('118 patent) issued on may 12, 1981) for the reasons stated in the Office Action on September 21, 2007.

The '118 patent teaches a food grade soybean oil obtained by a process different from the process used to prepare the food of the instant invention. In response to the Office Action, dated September 21, 2007 , the term "food" in claims 22-24 has been changed to "Food comprising a soy protein product".

In the Office Action, dated February 26, 2008, the Examiner maintains that the instantly claimed invention reads on soybean oil which inherently comprises oilbodies (e.g. oleosin, a soy protein). Applicants respectfully traverse and submit the following as support thereof.

The '118 patent discloses a food grade soybean oil obtained by a process different from the process used to prepare the food of the instant invention. In

summary , the process comprises the addition of water and a protein containing compound to the crude soybean oil, which contains various materials and compounds, such as phosphatides, lecithin, proteins, meal, seed remnants and the like. After the provision of the water and protein the entire system is then subjected to agitation, which is subsequently discontinued and the intermixed material allowed to settle for phase separation. The topmost or supernatant phase constitutes of the now treated soybean oil which is of food or commercial grade character. This layer may be withdrawn by any suitable means. The second layer, through analysis, has been found to be comprised substantially of protein material while the third layer from the top is water and the bottom-most layer is constituted substantially of lecithin. This is described in the second paragraph of the section titled "Description of the Invention" in the '188 patent. Furthermore in the seventh paragraph of the section titled "Description of the Invention" it is stated that;

"After such settling, the supernatant, or oil, was separated from the other layers and analyzed for protein content by the Kjeldahl nitrogen method. The protein level in the supernatant oil or that being separated from the treatment vessels as above described, was found to be less than 0.1 gram protein per 100 grams of oil (0.1%). A protein analysis of the crude soybean oil prior to treatment in accordance with the present invention showed a level of 1.5 gram protein per 100 grams of oil (1.5%)."

Thus, the goal of the method applied by '118 patent was to achieve the lowest amount of protein contaminants possible to make the oil suitable for consumption, which resulted in the presence of less than 0.1% of protein in the food grade soybean oil.

In contrast, the soy protein products as disclosed and claimed by Applicants constitute by definition a product made from soy containing a high protein content. On page 2 of the instant application it is stated "Soybean seeds contain from 35% to 55% protein on a dry weight basis. The majority of this protein is storage protein, which is hydrolyzed during germination to provide energy and metabolic intermediates needed by the developing seedling. The soybean seed's storage protein is an important nutritional source when harvested and utilized as a livestock feed. In addition, it is now generally recognized that soybeans are the most economical source of protein for human consumption. Soy protein or protein isolates are already used extensively for food products in different parts of the world. Much

effort has been devoted to improving the quantity and quality of the storage protein in soybean seeds."

Attention is kindly invited to Keshun Liu's book "Soybeans", 1997 by Chapman & Hall, chapter 6, pages 297, third paragraph (a copy of page 297 and the front pages of the book are included for the Examiner's convenience). It is stated on page 297 of Chapter 6 that; "*Modern soybean processing starts with solvent extraction to obtain crude oil and defatted meal* (emphasis added). *Most defatted meal is used for animal feed and only a small portion is further processed into different types of soy protein products for human consumption* (emphasis added). *Crude oil contains variable amounts of nontriglyceride materials. To remove some of these* ***impurities*** (emphasis added) *from the crude soy oil and convert it to a high quality edible oil, it is necessary to subject crude oil to a series of refining operations, including degumming to remove lecithin,…..*" Thus, oil and protein products are separated early on in the processing of soybean seeds and are characterized by their remarkable difference in protein content, which in food grade soybean oil constitutes merely an impurity, but is a required and abundant component of soybean protein products.

In view of the foregoing discussion, withdrawal of this ground of rejection of claims 22-24 is respectfully requested.

Claims 22-24 were rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Staswick et al. (Archives of Biochemistry and Biophysics, 223;1-8, 1983). It was stated on page 9 of the Office Action that Staswick et al. disclose soybean seeds having reduced levels of glycinin. The soybean seed storage proteins with reduced levels of glycinin would inherently constitute food.

Staswick et al. disclose the analysis of the 11S storage protein (glycinin) in the soybean cultivar "Raiden". Their findings suggest absence of certain acidic and basic polypeptides of the subunits that form the seed storage protein glycinin and the presence of a new acidic polypeptide which was called A6. On page 2 left hand column it is stated that "in addition to the missing acidic polypeptides the basic polypeptides pairing with the missing acidic ones are also not found".

The claims of the instant invention as amended above are directed to a

"*Food comprising a soy protein product prepared from soybean seeds having a reduced quantity of soybean seed storage protein ……...wherein the quantity of one or more members of a class of soybean seed storage protein subunits is reduced when compared to soybean seeds not comprising the* ***chimeric gene***

(emphasis added) *of step (a), and wherein the class of soybean seed storage protein subunits is selected from the group consisiting of: glycinin and β-conglycinin*. "

The specification on page 8, lines 17-28 states:

"***Chimeric gene***" (emphasis added) *refers to a gene that comprises heterogeneous regulatory and coding sequences not found in nature*."

Thus the food of the instant invention is distinguishable from the food that could be prepared from the soybean cultivar described by Staswick et al by the presence or absence of the chimeric gene. Methods for detection of chimeric genes in biological and in food material a very well known in the art and performed on a routine basis by those skilled in the art.

It is therefore believed that the claims of the instant invention are patentably distinct form the prior art.

In view of the foregoing, allowance of the above-referenced application is respectfully requested.

A petition for a three (3) month extension of time accompanies this response.

Please charge the fee required in connection with the extension of time, and any other fee that may be required to Deposit Account No. 04-1928 (E. I. du Pont de Nemours and Company).

Respectfully submitted,

/Lynne M. Christenbury/

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Dated: July 31, 2008